



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,973	12/04/2000	Nick N. Nguyen	ASP-7	3999

7590 03/30/2006

Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
----------	--------------

1744

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,973

Applicant(s)

NGUYEN ET AL.

Examiner

MONZER R. CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 01/09/2006

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (EP 0 321 908).

With respect to claim 1, The Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (figure 1:1) including the following: an inlet (figure 2:20), an outlet (figure 1:13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13).

With respect to claims 2-3 and 6, the Hatanaka ('908) reference teaches the following: a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite

Art Unit: 1744

direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1744

6. Claims 4, claim 5 (independently) and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908).

With respect to claim 4, the Hatanaka ('908) reference discloses an apparatus that includes a portion (figure 2, unlabeled space containing 9), which increases by at least 70% or more when compared with for example, structure 10 in figure 2. Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka ('908) apparatus in order to achieve the desired mixing time.

With respect to claim 5, The Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (figure 1, 1) including the following: an inlet (figure 2, 20), an outlet (figure 1, 13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13) having an labeled inner orifice space connected to 10. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and

Art Unit: 1744

residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time.

With respect to claims 7-8, the restriction flow (figure 1, 9A) of the Hatanaka ('908) apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. The Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction in the Hatanaka apparatus in order to increase residence time of the sterilant and thereby achieve the desired mixing time.

7. Claims 9-12, 14-16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0 321 908).

With respect to claim 9, the Cummings reference teaches a method for hydrogen peroxide vapor sterilization in a chamber (col.1, lines 12-16) including the following: creating temperature (col.3, lines 61-63) and vacuum pressure (col.3, lines 21-23 and lines 29-30) conditions within the vaporizer to vaporize the sterilant (col.1, lines 32-35), admitting the sterilant in its liquid phase into the vaporizer (col.3, lines 30-32), admitting no carrier gas into the vaporizer (the Cummings reference removes any air within the vaporizer and only injects hydrogen peroxide solution into the vaporizer), passing the sterilant in its vapor through a flow restriction (passage 20 in the figure due to its small diameter restricts the flow of the vapor going from the vaporizer 10 to the sterilization chamber 22) and passing the sterilant in its vapor phase out of the vaporizer (col.3, lines 36-46). However, the Cummings reference fails to teach passing the sterilant through a circuitous path. The Hatanaka ('908) reference teaches passing the sterilant through a circuitous path (in figure 2, the circuitous path is made up of the unlabeled volume containing 14 and baffles 9 as indicated by the arrows). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claims 15-16, the Cummings reference discloses using liquid hydrogen peroxide (col.2, lines 51-53) such that water is a stabilizing compound for the liquid phase of the sterilant.

With respect to claims 10-12 and 14, the Cummings reference fails to teach the following: passing the sterilant past a plurality of baffles, passing the sterilant in a first direction through an inner tube positioned concentrically within an outer tube, a second opposite direction between the inner tube and the outer tube, passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% and having the sterilant make at least two turns each of which are at least 90 degrees. However, the Hatanaka ('908) reference discloses the following: passing the sterilant past a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claims 19-20, the Cummings reference fails to teach that the sterilant remains within the vaporizer for at least 17 milliseconds or for at least 26 milliseconds. With respect to claims 19-20, the restriction flow (figure 1, 9A) of the Hatanaka ('908) apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction of the Cummings reference in order to increase residence time of the sterilant and thereby achieve the desired mixing time as taught by the Hatanaka reference.

8. Claims 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908) in view of Hatanaka et al (U.S.P.N. 4,797,255).

With respect to claims 13 and 17, the Hatanaka ('908) reference teaches a method for providing a sterilant in the vapor phase (col.3, lines 24-58) including the following: creating temperature (figure 1:16) and pressure (the heated gas flowing into inlet 6 in figure 2, is intrinsically pressurized and col.3, lines 26-28) conditions within the vaporizer (figure 2:1), admitting the liquid sterilant to be vaporized (figure 2:20), passing the sterilant through a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9), then passing the sterilant through a flow restriction (figure

2, unlabeled space immediately above the entrance point to 10) and passing the sterilant out of the vaporizer (figure 1:13). Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka ('908) circuitous path and the flow restrictor in order to achieve the desired mixing time. Regarding the disclosed percentage removal of the non-vaporizable components, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

With respect to claims 13 and 17, the Hatanaka ('908) reference fails to teach applying the vapor phase sterilant to a sterilization chamber. The Hatanaka ('255) reference discloses applying the vapor phase sterilant to a sterilization chamber (figure

4:1 and 29). Thus, it would have been obvious to one having ordinary skill in the art to at the time the invention was made to modify the method of Hatanaka ('908) reference to include a sterilization chamber as taught by the Hatanaka ('255) in order to sterilize packing articles independently of their forms with minimum consumption of hydrogen peroxide (col.1, lines 55-59).

With respect to claim 18, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

9. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0321908) in view of Leibold (DE 2639301).

With respect to claims 1 and 5, the Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (1) including the following: an inlet (20), an outlet (13), a circuitous path (9), creating temperature and pressure conditions to vaporize the sterilant (col.5, lines 28-35), passing the sterilant through a circuitous path (col.5, lines 35-57 and 9), and passing the sterilant out of the vaporizer (13). With respect to claims 1 and 5, the Hatanaka ('908) reference fails to teach the use of a flow restriction between the circuitous path and the outlet such that the flow restriction includes an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. With respect to claims 1 and 5,

Art Unit: 1744

the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). Further, the Leibold reference teaches applying the vapor phase sterilant to a sterilization chamber (page 5, lines 13-14). Regarding, the cross-sectional area of the flow restriction (7 has a cross-sectional area) in the Leibold reference of being no greater than about 25% of a cross-sectional area of the circuitous path (9) immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation. As a result, it would have been obvious to one having ordinary skill in the art to modify the apparatus of the Hatanaka ('908) reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claims 2-3 and 6, the Hatanaka ('908) reference teaches the following: a plurality of baffles (9), the circuitous path includes an inner tube (10) positioned concentrically within an outer tube (figure 2, space containing 9), the circuitous path includes a first portion (unlabeled arrows in the space containing 9) and a second portion (figure 2, unlabeled arrows in 10), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled arrows in 14 and unlabeled arrows in space containing 9, and unlabeled arrows in 10).

With respect to claim 4, the Hatanaka ('908) reference teaches an apparatus that includes a portion (unlabeled space containing 9), which increases by at least 70% or

Art Unit: 1744

more when compared with (10). Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan since Hatanaka recognizes the importance of mixing the carrier gas with the disinfection gas is crucial to producing a gas with a uniform density (col.4, lines 6-16). Note that mixing the gases involves time and this time interval is equivalent to the residence time of the gases within the apparatus.

With respect to claims 7-8, the flow restriction (7) in the apparatus of Leibold reference is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. On page 4, lines 1-9, the Leibold reference teaches that if a throttle or a nozzle or a valve is installed after the circuitous path and before the gas outlet of the vaporizer, then the speed of the emission of the vapor can be controlled. This statement means that depending on the intended use, if less flow rate of the vapor is desired to be emitted, then the flow restrictor will retain the vapor longer within the apparatus and the opposite is true.

10. Claims 9-12, 14,16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0321908) and further in view of Leibold (DE 2639301).

With respect to claim 9, the Cummings reference teaches a method for hydrogen peroxide vapor sterilization in a chamber (col.1, lines 12-16) including the following: creating temperature (col.3, lines 61-63) and vacuum pressure (col.3, lines 21-23 and lines 29-30) conditions within the vaporizer to vaporize the sterilant (col.1, lines 32-35),

admitting the sterilant in its liquid phase into the vaporizer (col.3, lines 30-32), admitting no carrier gas into the vaporizer (the Cummings reference removes any air within the vaporizer and only injects hydrogen peroxide solution into the vaporizer) and passing the sterilant in its vapor phase out of the vaporizer (col.3, lines 36-46). However, the Cummings reference fails to teach passing the sterilant through a circuitous path and passing the sterilant through a flow restriction. The Hatanaka ('908) reference teaches passing the sterilant through a circuitous path (in figure 2, the circuitous path is made up of the unlabeled volume containing 14 and baffles 9 as indicated by the arrows). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claim 9, the Hatanaka ('908) reference fails to teach passing the sterilant through a flow restriction; however, the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). As a result, it would have been obvious to one having ordinary skill in the art to modify the method of the Cummings reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claim 16, the Cummings reference discloses using liquid hydrogen peroxide (col.2, lines 51-53).

With respect to claims 10-12 and 14, the Cummings reference and the Leibold reference fail to teach the following: passing the sterilant past a plurality of baffles, passing the sterilant in a first direction through an inner tube positioned concentrically within an outer tube, a second opposite direction between the inner tube and the outer tube, passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% and having the sterilant make at least two turns each of which are at least 90 degrees. However, the Hatanaka ('908) reference discloses the following: passing the sterilant past a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform

Art Unit: 1744

density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claims 19-20, the Cummings reference and the Hatanaka ('908) reference fail to teach that the sterilant remains within the vaporizer for at least 17 milliseconds or for at least 26 milliseconds. With respect to claims 19-20, the flow restriction (7) in the apparatus of Leibold reference is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. On page 4, lines 1-9, the Leibold reference teaches that if a throttle or a nozzle or a valve is installed after the circuitous path and before the gas outlet of the vaporizer, then the speed of the emission of the vapor can be controlled. This statement means that depending on the intended use, if less flow rate of the vapor is desired to be emitted, then the flow restrictor will retain the vapor longer within the apparatus and the opposite is true. Thus, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a flow restriction as taught by the Leibold reference so that the speed of the emission of the vapor is controlled (page 4, lines 1-9).

11. Claim 15 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0321908) and Leibold (DE 2639301) as applied to claim 9 and further in view of in view of Feasey et al (U.S.P.N. 5,130,053).

With respect to claim 15, the Cummings reference, the Hatanaka reference and the Leibold reference fail to explicitly teach adding stabilizing compounds to the liquid sterilants. However, the Feasey reference discloses adding stabilizing compounds to hydrogen peroxide (col.1, lines 5-8). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of the Cummings reference to include stabilizing compounds as taught by the Feasey reference in order to decrease the rate of decomposition of the hydrogen peroxide by contacting it with such compounds (col.3, lines 36-40).

12. Claims 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0321908) in view of Leibold (DE 2639301).

With respect to claims 13 and 17, the Hatanaka ('908) reference teaches a method (col.3, lines 24-58) and an apparatus for vaporizing a sterilant (1) including the following: an inlet (20), an outlet (13), a circuitous path (9), creating temperature and pressure conditions to vaporize the sterilant (col.5, lines 28-35), admitting the sterilant to be vaporized (col.6, lines 44-47, 20, and 14), passing the sterilant through a circuitous path (col.5, lines 35-57 and 9), and passing the sterilant out of the vaporizer (13). With respect to claims 13 and 17, the Hatanaka reference fails to teach the use of a flow restriction between the circuitous path and the outlet. In addition with regard to claims 13 and 17, the Hatanaka ('908) reference fails to teach applying the vapor phase sterilant to a sterilization chamber. With respect to claims 13 and 17, the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). Further, the Leibold reference teaches applying the vapor phase sterilant to a

sterilization chamber (page 5, lines 13-14). Regarding, the cross-sectional area of the flow restriction (7 has a cross-sectional area) in the Leibold reference of being no greater than about 25% of a cross-sectional area of the circuitous path (9) immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation. In addition, with regard to the disclosed percentage removal of the non-vaporizable components, the Hatanaka reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

As a result, it would have been obvious to one having ordinary skill in the art to modify the method and apparatus of the Hatanaka reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claim 18, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the

discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

Remarks

13. The 112, paragraph I rejection in the action dated 07/18/2005 has been withdrawn along with the objection to claim 16. The drawings received on 11/21/2005 have been accepted.

Response to Arguments

14. Applicant's arguments filed on 01/09/2006 have been fully considered but they are not persuasive.

On page 8 of the Remarks section, applicant argues that, "Hatanaka et al. does not describe or teach operation below atmospheric pressure." The examiner disagrees. Claims 1 to 3 and 6 are apparatus claims and the Hatanaka reference teaches such features. Then the Hatanaka device is capable of having a pressure below atmospheric pressure.

On page 8 of the Remarks section, applicant argues that, "Hatanaka et al. fails to teach operation below atmospheric pressure and fails to teach a flow restriction." The examiner disagrees. As explained above, Claims 1 to 3 and 6 are apparatus claims and the Hatanaka reference teaches such features. Then the Hatanaka device is capable of having a pressure below atmospheric pressure. In addition, with respect to the flow restriction feature, the Hatanaka vaporizer includes a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13).

On page 8 of the Remarks section, applicant argues that, "The Hatanaka and Cummings processes operate under fundamentally different conditions. Cummings injects liquid sterilant into a vacuum with no carrier gas whereas Hatanaka injects sterilant into a flowing carrier gas." The examiner disagrees with the characterization of combining the Hatanaka and the Cummings references since Hatanaka teaches all the features of claim 9 except for passing the sterilant through a circuitous path and claim 9 is a method claim. The feature of having a carrier gas of lack of has nothing to do with the way the devices of both references operate since placing the circuitous means into the method of the Cummings device does not negatively alters its function. Clearly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

On bottom of page 8 into tope of page 9 of the Remarks section, applicant argues that, "Cummings et al. shows a block diagram of two chambers with a valved passage therebetween and the examiner attempts to describe flow restriction status to the passage." The examiner disagrees. The Cummings reference teaches passing the sterilant in its vapor through a flow restriction (passage 20 in the figure due to its small diameter restricts the flow of the vapor going from the vaporizer 10 to the sterilization chamber 22).

On page 9 of the Remarks section, applicant argues that, "One of ordinary skill in the art reading this reference would seek to have this flow be as fast and unimpeded as possible." The examiner disagrees since the Cummings reference intention in having a flow restriction between the two chambers is to achieve a certain temperature, pressure and concentration of the sterilant prior to admitting it into the second chamber. Impeding the flow is necessary for the operation of the Cummings reference.

On page 9 of the Remarks section, applicant argues that, "Claim 9 contains the limitation of admitting no carrier gas into the vaporizer. Both of these Hatanaka references rely upon a carrier gas. Accordingly, they fail to teach the claim invention." The examiner disagrees since the Cummings reference removes any air originally presence within the vaporizer and instead only injects hydrogen peroxide solution into the vaporizer and this feature corresponds to "admitting no carrier gas into the vaporizer".

On page 10 of the Remarks section, applicant argues that, "No throttle would be necessary to prevent surges and would be contraindicated as it would add an unnecessary pressure drop into the system thus reducing energy efficiency." The examiner disagrees. Adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed such that design modifications, i.e., pressure drop or other problems are a matter of routine experimentation that are within the scope of the artisan.

On page 10 of the Remarks section, applicant argues that, "As can be seen, such is not necessary when the rate is controlled by the rate of drops coming out of the nozzle." The examiner disagrees. Adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed so that any possible harm to surroundings or personnel is completely prevented. In addition, the flow restrictor of the Leibold reference gives the added advantage of storing the sterilant in case of interruptions in the supply source resulting in a continuous dispense of the sterilant.

Conclusion

15. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Art Unit: 1744

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji
Patent Examiner
AU 1744
03/07/2006



GLADYS J.P. CORCORAN
PRIMARY EXAMINER